Saudi Food & Drug Authority (SFDA)
SAFETY COMMUNICATION

27/02/2018

Potential Cardiovascular Risks Associated with Clarithromycin Use in Patients with Heart Diseases

The Saudi Food and Drug Authority (SFDA) would like to keep Healthcare professionals (HCPs) updated concerning the increased risk of cardiovascular adverse events, namely; heart failure, exacerbation of existing heat disease, or cardiac death following clarithromycin use. These effects possibly become more intense in patients who were diagnosed with any kind of coronary heart diseases (CHD). The risk might persists and causes latent events even after clarithromycin discontinuation.

The promoter for releasing this warning statement was a ten-year-long clinical trials called: **CLARICOR**[1]. The main objective of CLARICOR study was to investigate the effects of clarithromycin in patients with stable CHD. The study findings showed that the patients treated with clarithromycin for a period of two weeks are at higher risk of ending up with cardiac death after the first year of follow-up through the end of study period. Two observational studies [2, 3], also, found an evidence of long-term risks of serious heart problems or death associated with clarithromycin use, in patients with or without CHD.

The SFDA is spreading tranquility among concerned healthcare providers as this safety issue is taking care of by the national pharmacovigilance and drug safety center (NPC). Now, the center is searching in the recent literature and other related safety data concerning such a safety concern and will release the results of this review after a reliable evidence become conclusive. Meanwhile, the SFDA advises HCPs to take extra caution when prescribing clarithromycin to a patient with co-existing coronary heart diseases by recommending

another safe alternative antibiotic. Patients should be advised to seek for medical assistance when they experience any signs or symptoms of heart originated problems, such as chest pain, shortness of breath, pain or weakness in one side of the body, or slurred speech.

Report Adverse Drug Events (ADEs) to the SFDA

The SFDA urges healthcare professionals to report ADEs resulted from using Clarithromycin containing products to the SFDA using the following contact information:

National Pharmacovigilance and Drug Safety Center (NPC)
Saudi Food and Drug Authority-Drug sector
3292 Northern Ring Road
Al Nafal District
Riyadh 13312 – 6288
Kingdom of Saudi Arabia
Reporting hotline: 1999
Fax: 01 2057662
Email: NPC.Drug@sfda.gov.sa
Webpage: www.sfda.gov.sa/npc

Reference:

(1) Winkel P, Hilden J, Fischer Hansen J, et al, Clarithromycin for stable coronary heart disease increases all-cause and cardiovascular mortality and cerebrovascular morbidity over 10 years in the CLARICOR randomized, blinded clinical trial. International Journal of Cardiology 2015; 182:459-465.

(2) Schembri S, Williamson PA, Short PM, et al. Cardiovascular events after clarithromycin use in lower respiratory tract infections: analysis of two prospective cohort studies. BMJ 2013 Mar 20; 346.

(3) Mosholder AD, Lee JY, Zhou EH, et al. Long-term risk of acute myocardial infarction, stroke and mortality in adult outpatients treated with clarithromycin: a retrospective cohort study in the Clinical Practice Research Datalink. Journal of Epidemiology, kwx319, https://doi.org/10.1093/aje/kwx319 .